

Applicants respectfully disagree with this rejection. The Examiner states that the amendment of April 17, 2001 introduces new matter and that claims 94-98, 107-111 and 127-139 are not supported in the specification. The Examiner cites the phrases "allelic frequency of at least 0.20" and "polymorphic array" as not supported in the specification.

Support for "polymorphic array" is found at for example, pages 42 lines 27-34 of the specification "To perform such polymorphic analysis, the presence or absence of a set of polymorphisms (i.e. a "polymorphic array") is determined for a set of the individuals, some of which exhibit a particular trait, and some of which exhibit a mutually exclusive characteristic (for example, with respect to horses, brittle bones vs. non-brittle bones; maturity onset blindness vs. no blindness; predisposition to asthma, cardiovascular disease vs. no such predisposition)." Thus, the phrase "polymorphic array" is specifically supported in the specification.

Support for "allelic frequency of at least 0.20" or 20% is found for example at pages 43, lines 2-8 of the specification. "Alleles that do not segregate randomly with respect to a trait can be used to predict the probability that a particular animal will express that characteristic. For example, if a particular polymorphic allele is present in only 20% of the members of a species that exhibit a cardiovascular condition, then a particular member of that species containing that allele would have a 20% probability of exhibiting such a cardiovascular condition." Thus, the phrase "allelic frequency of at least 0.20" is specifically mention in the specification. Accordingly, Applicants respectfully request withdrawal of this rejection.

**Second Rejection under 35 U.S.C. §112, first paragraph**

The Examiner has rejected claims 94-98, 107-111, and 127-139 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification

in such a way as to reasonably convey to one skilled in the art to make or use the invention. Applicants respectfully disagree.

The Examiner cites factors from *In re Wands*, 88 F.2d 731 (1988): 1) the quantity of experimentation necessary; 2) the amount of guidance presented; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. The Examiner also cites Carrico U.S. Patent No. 5,200313 for specific conditions and variables in hybridization. The Examiner concludes that the specification does not allow one skilled in the art to make or use the claimed invention.

Applicants wish to re-emphasize that the invention as presently claimed is completely independent of any typing or genotyping or hybridization methodologies. Applicants were the first to recognize that SNPs are pervasively and densely distributed throughout the genome and can be used as markers in genetic maps and for association with traits. The embodiments of claimed invention are derived from Applicants' discovery that the distribution and density of SNPs in a mammalian genome were informative and that combining SNPs would provide valuable genetic information for any species. Before the present invention, no-one understood or even contemplated that using a combination of SNPs could provide a powerful approach to genetic analysis. Indeed, Applicants' invention was pioneering. Moreover, Applicants, in their specification, teach the advantages of SNPs for genetic analysis. See, for example, pages 13-15. Applicants teach and demonstrate in their specification the additive power of using a combination of SNPs. See, for example, Figure 4 and 5. Further, Applicants teach that even at high allelic frequencies, using a combination of SNPs provides highly accurate genetic analysis. See, for example, pages 38-42. Thus, the type of SNP identification method used to identify the SNP is not critical to the invention.

The Examiner asserts that the present specification does not teach specific factors for hybridization, purification, base compositions of the probe, sequence homology, incubation temperature, ionic strength, nucleic acid concentration, and denaturing reagents. (Office action pages 7-8). All these factors were well known in the art at the time of filing the application. DNA could be identified by any standard hybridization methods and these among other methods were well known to those skilled in the art at the time of filing. See for example, Sambrook, J. et al. (Eds.), Molecular Cloning, Second Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York (1989).

The Examiner is arguing that the specification does not enable one skilled in the art to make or use the claimed invention based on variable factors such as hybridization conditions used to identify SNPs. But the critical part of the presently claimed invention is directed to what is done with the SNP **after** it is identified, not how the SNP is identified. The claimed invention is based on the discovery that combining SNPs would provide valuable genetic information for any species. Thus, the type of SNP identification method used is not critical to the invention. The conditions for hybridization are also not critical to the claimed invention.

Applicants submit that the present invention as claimed is fully enabled and allows one skilled in the art to make or use the claimed invention. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

In view of the foregoing remarks set forth above, reconsideration and allowance are respectfully solicited.

Applicants: Goelet et al.  
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If the Examiner has any questions or comments, the Examiner is cordially invited to contact Applicants' attorney at the telephone number provided below.

Respectfully submitted,



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